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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,287	03/26/2002	Denis Labarre	427.056	9376

20311 7590 08/14/2003

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EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 08/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/089,287

Applicant(s)

LABARRE ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 28-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 and 28-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### DETAILED ACTION

Examiner acknowledges receipt of IDS and priority document filed 03/20/02 and preliminary amendment A filed 03/26/02.

#### *Priority*

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

#### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-21 and 28-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite because it is not apparent how a polysaccharide could be non-saccharidic. Claim 1 recites in line 7 "at least one of the non-saccharidic polysaccharides ...."

3. Claim 1 recites the limitation "each non-cross-linked polycarboxylic copolymer" in lines 3 and 4. There is insufficient antecedent basis for this limitation in the claim.

Claim 1 is interpreted to expedite prosecution as follows and support is found on page 1, lines 9 and 10 of applicants' specification:

For examination purposes claim 1 is --- A cross-linked copolymer prepared from a reaction between a cross-linking agent that has at least two amine functions and non-cross-linked

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polycarboxylic copolymer where the non-cross-linked polycarboxylic copolymer comprises at least one non-cross-linked polysaccharide and at least one non-saccharidic non-cross-linked polymer and where at least one of the non-saccharidic non-cross-linked polymer is polycarboxylic.---

4. Claim 1, line 5 recites the term "other" and the term "other" renders the claim indefinite because the claim include elements not actually disclosed (those encompassed by "other"), thereby rendering the scope of the claim unascertainable. See MPEP § 2173.05(d).

5. Claim 2 requires that the polysaccharide be non-polycarboxylic. However, in claim 1 the polysaccharide is a polycarboxylic copolymer (lines 3 and 4 of claim 1).

6. Claim 3 recites the limitation "non-polycarboxylic polysaccharide" in lines 1 and 2. There is insufficient antecedent basis for this limitation in the claim. There is no recitation of non-polycarboxylic polysaccharide in claim 1.

#### *Claim Rejections - 35 USC § 102*

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002

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do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. Claims 1-18, 20, 21 and 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by El et al. (WO 98/08897, English translation provided by applicants).

El discloses cross-linked copolymers that are based on non cross-linked polycarboxylic polymers and cross-linking agent, which has at least two amine functions; the cross-linked copolymer comprises at least one polycarboxylic polysaccharide and at least one non cross-linked polycarboxylic polymer that is not a polycarboxylic polysaccharide (page 1, line 16 to page 2 line 5). The non cross-linked polycarboxylic polysaccharide is selected from glycosaminoglycan, pectinic acid (pectin), alginic acid, carboxymethyldextran, carboxymethylcellulose (page 2, lines 6-11 and 21-24) and these polysacchrides are not polycarboxylated. Non polysaccharide polycarboxylic polymers are selected from poly(glutamic acid), poly(aspartic acid), poly(acrylic acid), poly(methacrylic acid) and EUDRAGIT L and S (page 2, lines 11-15). The cross-linking agents are selected from polyamines, triamines, and diamines, proteins, polylysine, chitosan and melamine and spermine, and hexanediamine is specifically disclosed diamine (page 3, lines 6-19). El discloses degradation of the polycarboxylic polysaccharide in the composition by the flora of the colon (page 7, lines 1 and 2). El also discloses a method of preparing the cross-linked polymer where the method comprises reacting the non cross-linked polycarboxylic polymers in the presence of an activators and a cross-linking agent that comprises at least two amines, in an aqueous medium

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(page 4, lines 3-7). The activator is selected from carbodiimides, quinoline and mixed anhydrides (page 5, lines 12-23). The composition of EI comprises active ingredients such as 5-aminosalicylic acid, antineoplastic agents, antispasmodic and chemotherapeutic agents (page 7, lines 8-19), and inert support or excipient, which is at least one cross-linked co-polymer (page 6, lines 1-3). The teaching of EI meets the limitations of the claims.

9. Claims 1-18, 20, 21 and 28-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Lambert et al. (US 6,229,009).

The applied reference has common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Lambert discloses cross-linked copolymer that is based on at least one non-cross-linked polycarboxylic polysaccharide and at least one second non-cross-linked polycarboxylic polymer that is not a polycarboxylic polysaccharide (abstract). The non-cross-linked polysaccharide is selected from glycosaminoglycans, pectinic acid, alginic acid, carboxymethyldextran and carboxymethylcellulose (column 1, lines 49-56). The non-saccharidic polycarboxylic polymer is selected from poly(glutamic acid), poly(aspartic acid), poly(acrylic acid), poly(methacrylic acid) and EUDRAGIT L and S (column 1, lines 57-62). The cross-linking agent comprises at least two amine functions and examples are polyamines, triamines, diamines, proteins and hexadamine is an example of a diamine (column 2, lines 20-39). Lambert also discloses a

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process for preparing the cross-linked copolymer and the process comprises reacting non-cross-linked polycarboxylic polymers with the cross-linking agent that has at least two amine functions, in the presence of an activator and the reaction is carried out in an aqueous media (column 2, line 52 to column 3 line 36). The activator is selected from carbodiimides, quinoline derivatives or mixed anhydride (column 3, lines 37-54). Lambert further discloses a pharmaceutical composition that comprises at least one active agent, at least one cross-linked copolymer as an inert support or excipient (column 3, lines 59-66); the composition is degradable by the flora of the colon and can be directly administered at the level of the colon (column 4, lines 25-32 and 40-47). See also claims 1, 2 and 4-21. The teachings of Lambert meet the limitations of the claims.

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over El et al. (WO98/08897) in view of Heidel et al. (US 5,219,971).

El clearly teaches the cross-linked polymers of the instant application except that the reaction of the non-saccharidic polymer with the polysaccharide is not done in an inert atmosphere. However, Heidel discloses grafting olefinically unsaturated carboxylic acid onto a polysaccharide in the presence of nitrogen (abstract, column 4, line 65 to column 7 line 13 and

example 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the cross-linked polymer of EI in aqueous medium. One having ordinary skill in the art would have been motivated to prepare the polymer in the absence of air with the expectation of polymerizing the non cross-linked copolymers.

### ***Double Patenting***

12. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

13. Claims 1, 4-6, 9-12, 14, 17, 18, 20 and 21 rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 2, 4-9, 13, 14, 16, 17 and 18 of prior U.S. Patent No.

6,229,009. Claim 1 is identical in scope compared to claim 1 of US 6,229,009 even though the wording between the claims is slightly different. Note that claim 1 is a cross-linked copolymer prepared from a reaction between a cross-linking agent that has at least two amine functions and non-cross-linked polycarboxylic copolymer where the non-cross-linked polycarboxylic copolymer comprises at least one non-cross-linked polysaccharide and at least one non-saccharidic non-cross-linked polymer and where at least one of the non-saccharidic non-cross-linked polymer is polycarboxylic. This is a double patenting rejection.

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or



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improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claim 13 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 11 of U.S. Patent No. 6,229,009. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim because the examined claim is either anticipated by or would have been obvious over the reference claim. See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 13 is generic to all that is recited in claim 11 of US 6,229,009. That is claim 11 of US 6,229,009 falls entirely within the scope of claim 13, or in other word, claim 13 is anticipated by claim 11 of US 6,229,009.

16. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara  
Patent Examiner  
Tech. Center 1600

